

**Appl. No. 09/807,457**  
**Amdt. dated May 19, 2005**  
**Reply to Office Action of January 25, 2005**

**REMARKS/ARGUMENT**

This amendment responds to the Office Action of January 25, 2005.

Initially, Applicant gratefully acknowledges the Examiner's courtesy in granting his representatives an interview on April 29, 2005, during which the issues remaining in the case were discussed. Specifically, as reflected by the Interview Summary, a proposed amendment was presented, which the Examiner indicated would not likely be entered at this stage of the prosecution. Examples showing the materials of the present invention and those of the cited art were also shown to the Examiner.

Claims 1-13, 16-18, 22, 25, 27-30, 33-38, 40-49, and 51-52 are pending in the application with claims 14, 15, 19-21, 23, 24, 26, 31, 32, 39, and 50 having been canceled, claims 1, 28, 36, and 51 having been currently amended, and new claim 52 added. New claim 52 is former claim 26 re-written in independent form. The total number of claims pending in the application remains the same, owing to the cancellation of claim 26.

Support for the amendments to the specification are supported in the application as originally filed in claim 22. Support for the amendment to claim 22 can be found in the specification on page 6, line 11, through page 7, line 8. Entry of the amendments is respectfully requested as it is believed they put the application in condition for allowance or in better condition for appeal.

**Appl. No. 09/807,457**  
**Amdt. dated May 19, 2005**  
**Reply to Office Action of January 25, 2005**

The specification has been objected to as failing to provide proper antecedent basis for the claimed subject matter. According to the Examiner, support has not been found within the specification for the amended subject matter of claims 1, 22, and 51, and correction has been required.

In a related matter, claims 1-13, 16-18, 22, 25-30, 33-38, and 40-51 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. According to the Examiner:

"The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While applicant has stated at line 7 of page 1 of the specification that a mouldable material can be converted to a stable form by curing, applicant has failed to disclose a process step of "stabilizing", *per se*, though applicants have amended the claims to include such a process step. It is unclear if an operation other than curing is denoted by the "stabilizing" language."

With regard to claim 22, support therefor appears on page 7, lines 10-16; page 9, lines 11, 25-27, and the paragraph bridging pages 9 and 10; and in claim 22; all as in the application as originally filed.

**Appl. No. 09/807,457**  
**Amdt. dated May 19, 2005**  
**Reply to Office Action of January 25, 2005**

Further "stabilizing and curing" in claims 1 and 51 has been amended by deletion of "stabilizing and".

Accordingly, it is requested that the objection to the specification and the rejection of claims 1-13, 16-18, 22, 25-30, 33-38, and 40-51 under 35 U.S.C. 112, first paragraph, be withdrawn.

Claims 1-13, 16-18, 22, 25-30, 33-38, and 40-51 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

According to the Examiner, "Within line 10 of claims 1 and 51, it is unclear how to interpret the amended language pertaining to "respectively". Is applicant requiring the component that is at least trifunctional to be NCO functional and the other one that is at least difunctional to be OH functional?

Claims 1 and 51 have been amended by changing:

"wherein at least one of the starting components is at least trifunctional and the other one is at least difunctional, with regard to NCO or OH groups, respectively"  
to read:

"wherein at least one of the starting components is at least trifunctional with regard to NCO groups and the other one is at least difunctional with regard to OH groups, or at least one of the starting materials is at least trifunctional with regard

**Appl. No. 09/807,457**  
**Amdt. dated May 19, 2005**  
**Reply to Office Action of January 25, 2005**

to the OH groups and the other one is at least difunctional with regard to the NCO groups"

which defines what Applicant intended to be the meaning of "respectively".

Accordingly, it is requested that the rejection of claims 1-13, 16-18, 22, 25-30, 33-38, and 40-51 have been rejected under 35 U.S.C. 112, second paragraph, be withdrawn.

Claims 17 and 48-51 have been rejected under 35 U.S.C. 102(b) as being anticipated by EP 262488.

EP 262 488 has been cited and extensively discussed in the present specification. The essential difference between EP 262 488 and the present invention being the fact that the polyurethane material disclosed and claimed in EP 262 488, which is similar to the polyurethane material of the "preform" of the present invention, is used as a filler material in the production of shapeable and curable compositions for making dental devices.

More specifically, the '488 polyurethane-material is produced in the form of hard, solid lumps, consisting of polyurethane and silicon dioxide (approx. weight ratio 50:50; see examples 1 and 2), which lumps are ground and milled into powders and thereafter mixed with the organic, non-polyurethane-matrix material of the dental composition (see, e.g., examples 17 and 18). The mixture of organic matrix material and silylated polyurethane-filler material is then cured by radical triggered polymerization, wherein the reactive double bonds shall react with the reactive groups of the organic matrix material in order to establish a strong connection between the matrix and the filler (see EP 262 488 p.2, lines 36-39 reading:

"It is the object of the invention to develop an organic filler which due to its high content of reactive groups that are co-polymerisable with the matrix monomers, establishes a strong connection between filler and matrix, and which after final polymerisation yields a material that possesses substantially improved tensile strength, loading capacity and abrasion resistance.")

That is, the '488 product is a dental composition formed from an organic, non-polyurethane matrix and a reactive, silylated polyurethane filler in powder form, wherein during final, radical-triggered polymerisation the silylated polyurethane filler reacts via its reactive double bonds with the organic matrix material and, optionally, also with a binder material added to the non-polyurethane matrix.

On the other hand, the moulded body of the present invention is a shaped and cured molded body having a polyurethane-matrix already in its preform, and optionally additives, wherein during final, radical-triggered polymerisation, the reactive double bonds of the polyurethane matrix react with each other, thus stabilizing and curing the shaped structure of the polyurethane matrix preform.

Moreover, the inventors of EP 262 488 did not realize that the polyurethane-filler material would have had flexible, optionally even elastic, properties when manufactured without addition of silicon dioxide. Such properties were neither anticipated nor sought as the sole intended use of the material was as a filler material in comminuted, powdered form in the

**Appl. No. 09/807,457**  
**Amdt. dated May 19, 2005**  
**Reply to Office Action of January 25, 2005**

manufacture of improved curable dental compositions (see also claim 11). Accordingly, there was no motivation for a person of ordinary skill in the art to:

- take the '488 polyurethane filler material out of its known context,
- in a non-powdered form,
- to modify it by shaping steps, and
- to use it as a matrix rather than a filler material for non-dental applications.

The following Table is presented to summarize and clarify the differences between the currently claimed invention and the product and process of EP 262 488.

Present Claim 1	EP 262 488
Starting Materials (to be subjected to non-radical polyaddition reaction)	
polyisocyanate, unsaturated polyhydroxy monomer	polyisocyanate, unsaturated polyhydroxy monomer, <i>silicon dioxide</i>
Resulting Polyurethane Preform	
Shaped ,crosslinked, flexible PU body	Shaped ,crosslinked, <i>hard</i> PU body
Further Processing	
Final curing of preform by radical induced polymerization of available double bonds.	<i>Comminuting hard preform to powder</i> (Examples 1-11), add the powder to polymerizable monomer components, adding additional silicon dioxide to <i>make a paste</i> , and finally <i>curing the paste</i> by radical induced polymerization of available double bonds to make a dental device (Examples 13-15, 17, 18)
Resulting End Product	
Rigid cured shaped body of desired form having a crosslinked PU-matrix reinforced by additional crosslinking through said radical induced double bond reactions;	Rigid cured shaped body of desired form (e.g., dental inlay) having an organic <i>non-PU matrix</i> reinforced by reaction with the available double bonds of the <i>admixed powdered PU-preform</i> material:
Direct conversion of the flexible PU preform, i.e., without addition of further components.	<i>Reaction product</i> of powdered PU preform with <i>additional organic monomers</i> and inorganic filler material.

Even where the present invention utilizes filler or fiber material to further reinforce the end product, such fiber or filler material is added to the starting components, thus always resulting in a flexible polyurethane preform that is subsequently converted into its end form just by radical induced polymerization, i.e., *without the addition of any further reactive ingredients*, contrary to the method of EP 262 488.

It should be emphasized that the inevitable structural differences of the present polyurethane bodies (polyurethane backbone, radically crosslinked with itself) and the dental devices of EP 262 488 (non-PU backbone radically reacted with powdered PU preform) are also verifiable by analytical methods.

The Examiner is required to support a rejection based upon anticipation with a citation that discloses each and every claimed element. EP 262,488 does not do this. Accordingly, it is requested that the rejection of claims 17 and 48-51 under 35 U.S.C. 102(b) as being anticipated by EP 262488 be withdrawn.

Claims 1-13, 16-18, 22, 25-30, 33-38, and 40-51 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Verleg et al. (U.S. Patent No. 5,286,832) or Smith (U.S. Patent No. 6,114,402) or EP 269071, each in view of EP 262,488.

Verleg et al. disclose a process for the manufacture of cast, injection moulded or compression moulded articles by curing a resin composition in a desired shape using catalysts, and allowing the shaped piece to post-cure under such conditions that an HDT of at least 150°C is obtained. The resin composition comprises a polyisocyanate, an ethylenically unsaturated



**Appl. No. 09/807,457**  
**Amdt. dated May 19, 2005**  
**Reply to Office Action of January 25, 2005**

monomer and a vinyl ester compound, and the vinyl ester compound contains on average about two to about six (meth)acrylate groups and on average about two to about six hydroxyl groups, and has a molecular weight higher than 300.

Smith discloses a polyurethane composition that provides a rigid polyurethane foam suitable for use as a core material in a composite laminate and which polyurethane composition includes an additive compound or oligomer-prepolymer having hydroxy groups for reaction with the diisocyanate of the polyurethane or which has been prereacted with a diisocyanate and which contains after the polyurethane reaction ethylenically unsaturated groups, like allyl or acrylic groups, to react with an unsaturated polyester resin.

EP 269 071 discloses the manufacture of a polyurethane-based material for making dental impressions, wherein in a first step a hydroxy-group containing oligomer (polypropylene glycol) which does not contain unsaturated reactive double bonds is reacted with diisocyanate to form a first polyurethane product having 2 isocyanate end groups (see claim 19). In a second step, the polyurethane material of the first step is reacted with an unsaturated hydroxyl substituted organic ester (e.g. hydroxyethylmethacrylate) to form a derivated polyurethane. In a third step, the derivated polyurethane material is reacted with a lower alkyl diol and in yet another step the resulting derivated polyurethane material is still reacted with a further compound obtained from the reaction of a diisocyanate and an unsaturated organic acid ester. The polyurethane-preforms of EP 269 071 do not contain at least 0.5 mmole/g of reactive double bonds, because they are made prevailingly from a hydroxy-group containing oligomer that has no reactive double bonds.

**Appl. No. 09/807,457**  
**Amdt. dated May 19, 2005**  
**Reply to Office Action of January 25, 2005**

Not only does EP 269, 071 disclose a different method of making the polyurethane product (i.e. a four-step-process vis-a-vis a two-step-method of the present invention), it also utilizes different starting materials and therefore yields a different final product.

It is not seen how Verleg et al. and Smith would add anything to EP 262 488 to arrive at the present invention. In paragraph 7 of the Office Action, the Examiner correctly points out that both references teach the reaction of ethylenically unsaturated PU compositions upon exposure to heat or radiation. However, this is also disclosed in EP 262 488.

Moreover, contrary to the Examiner's assertion in paragraph 8, there was absolutely no motivation for a person skilled in the art to modify the teachings of EP 262 488 by applying any elements known from the other cited prior art references, including EP 269 071. This is so because EP 262 488 exclusively focuses on the development of an improved material for making dental impressions and related dental devices, which material should be in the form of a curable paste that would, upon final cure, have improved properties as to rupture, pressure and abrasion resistance (see page 2, lines 36-39 of EP 262 488), and that would essentially avoid shrinkage of the cured material.

The solution provided by EP 262 488 is the development of a reactive PU filler material which itself contains inorganic filler and which is added to polymerizable organic monomers and additional inorganic filler material, mixed to form a paste and subsequently cured by radiation (Examples 13-15) or application of heat (Examples 17-18). It was not recognized then that the PU filler material would have had other properties and thus additional applications, if produced

according to the present claim 1. Nor was it recognized throughout a period of *eleven years* following the filing date of EP 262 488.

Articles of manufacture that are moulded bodies prepared by the process of the invention are also claimed. Compositions of matter are not claimed. It has been acknowledged in the present specification that the polyurethane compositions employed in the practice of the present invention are similar to those described in EP 262488 (see, for example, page 4, lines 19 and 20.) However, as pointed out above, the essential difference between EP 262 488 and the present invention is that the polyurethane material disclosed and claimed in EP 262 488, which is similar to the polyurethane material of the "preform" of the present invention, is used as a filler material in the production of shapeable and curable compositions for making dental devices, whereas the moulded body of the present invention is a shaped and cured molded body having a polyurethane matrix already in its preform, and optionally additives, wherein during final, radical-triggered polymerisation, the reactive double bonds of the polyurethane matrix react with each other, thus stabilizing and curing the shaped structure of the polyurethane matrix preform. Thus, the article of manufacture of the present invention is different from that disclosed in EP 262 488. They are different because the processes employed for producing them are different.

Further, since the polyurethane preform of EP 262 488 was exclusively made to be ground to a powder for use as a dental filler material, it was necessary to manufacture the PU-preform in the form of a hard solid body. A flexible or even elastic PU-preform as recited and claimed according to the present invention would not have been grindable to powder unless after

deep-freezing to obtain a brittle, breakable, and grindable material. Therefore, it does not appear that EP 262 488 would provide any motivation to modify the concept of the invention disclosed and claimed therein.

Neither Verleg et al., Smith, nor EP 269, 071 disclose or suggest the currently claimed method of the present invention. In particular, Verleg et al. does not teach preparing a mixture of isocyanate and unsaturated monomers having both reactive double bonds and hydroxyl groups and subjecting the mixture to *a polyaddition reaction that is not triggered by radicals*. Verleg et al. teach mixing ethylenically unsaturated monomer with a vinyl ester compound and a polyisocyanate and promoting copolymerization with a free radical catalyst (see column 5, line 58 through column 6, line 15). Smith does not teach preparing a mixture of isocyanate and unsaturated monomers having both reactive double bonds and hydroxyl groups, as starting components, wherein at least one of the starting components is at least trifunctional with regard to NCO groups and the other one is at least difunctional with regard to OH groups or wherein at least one of the starting components is at least trifunctional with regard to OH groups and the other one is at least difunctional with regard to NCO groups; subjecting the mixture to a polyaddition reaction; and subjecting the mixture before or during the polyaddition reaction to a shaping step. EP 269, 071 discloses a different method of making a polyurethane product (i.e. a four-step-process vis-a-vis a two-step-method of the present invention), and utilizes different starting materials and therefore yields a different final product.

Further, pursuant to the Examples disclosed in EP 269 071, at least 70 to 85 percent by weight of the organic ingredients of the PU dental material comprises a *saturated* hydroxy component (i.e., polypropylene glycol), while the amount of unsaturated monomer is around 5% (Example 1) or less (Example 4). Compared to the amounts of ethylenically unsaturated monomers of the present invention (i.e., more than 50% by weight, see Examples 1-3), it is more than unlikely that the resulting products of EP 269 071, prior to final curing by photopolymerization, would have at least 0.5 mmole/g of non-extractible double bonds. But even if they would, they would be vastly different from the products of the present invention because the backbone of the products of EP 269 071 is a *saturated polyurethane matrix* obtained from a PU prepolymer having free isocyanate groups, which prepolymer is then derivated in a subsequent reaction step by reaction with low amounts (maximum of 5% by weight) of ethylenically unsaturated monomer, followed by further reaction steps. Whereas the preforms of the present invention comprise an ethylenically unsaturated PU matrix obtained by reaction of unsaturated monomers having hydroxyl groups with an isocyanate component.

Moreover, in Example 1, it is disclosed (page 12, line 25) that the unsaturated monomer HEMA is added in excess, thus resulting in the presence of extractible double bonds, contrary to the requirements of the present invention.

Taken together the above arguments are believed to unambiguously demonstrate the substantial differences between the disclosure of EP 269 171 and currently claimed invention. Given the fact that both EP 269 071 and EP 262 488 are in the field of dentistry/dental materials,

**Appl. No. 09/807,457**  
**Amdt. dated May 19, 2005**  
**Reply to Office Action of January 25, 2005**

it is not seen how a person of ordinary skill in the art would be motivated to modify the product or process of EP 269 071 using the elements of EP 262 488, or vice versa, to arrive at the present invention as claimed in claims 1 and 51.

Further, the Examiner's attention is directed to new claim 52, which is directed to a preferred aspect of the present invention wherein polyurethane moulded body is foamed. Claims 16 and 34 are also directed to this preferred aspect. It is submitted that these claims are even farther removed from the disclosures of the cited art than are the remaining claims in the application.

Accordingly, it is requested that the rejection of claims 1-13, 16-18, 22, 25-30, 33-38, and 40-51 under 35 U.S.C. 103(a) as being unpatentable over Verleg et al. or Smith or EP 269071, each in view of EP 262,488, be withdrawn.

In view of the foregoing, it is submitted that this application is now in condition for allowance and an early Office Action to that end is earnestly solicited.

Respectfully submitted,



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